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The Drug Enforcement Administration, Controlled Substances and Pain Management

by
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Introduction

This article is intended to clarify the DEA's position on the use of controlled substances in pain management, while focusing on controlled substance diversion and what healthcare professionals can do to minimize the diversion of controlled pharmaceuticals.

The DEA's Policy & Pain Management

In written testimony before the House Judiciary Committee on the Pain Relief Promotion Act of 1999, the American Pharmaceutical Association attributed the under treatment of pain in the United States to six factors. Foremost among these factors was practitioner concern about regulatory oversight. The other factors include: lack of medical training, antiquated fear of addiction, inadequate reimbursement mechanisms, lack of routine assessment, and misunderstanding about side effects. (American Pharmaceutical Association, Statement on Pain Relief Promotion Act of 1996 (H.R. 2260), June 24, 1999.) The implication is that practitioner fear of regulators produces a chilling effect on the use of controlled substances to treat pain effectively.

A common misperception among medical professionals is the belief that the DEA's regulations and policies impede effective pain management. For those of you unfamiliar

with the DEA's pain position, the reality is that practitioner fear of the DEA is unwarranted where controlled substances are used appropriately. In fact, far from prohibiting controlled substance use, the Controlled Substances Act, which Congress enacted and which the DEA enforces, its implementing regulations and the DEA all encourage their use where appropriate. The operative word, however, is "appropriate."

The DEA's Policy Cornerstones

The DEA's position with respect to controlled pharmaceuticals used in pain management rests upon four cornerstones and any discussion about the DEA and pain management must begin there. The Controlled Substances Act and the DEA recognize that many controlled substances "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." *Title 21 of the United States Code (21 U.S.C.), § 801(1)*. Secondly, the regulations state that practitioners are not limited in their ability to administer or dispense narcotic drugs to individuals with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts. *Title 21, Code of Federal Regulations (21 CFR), § 1306.07(c)*.

Thirdly, the regulations require that for a prescription to be valid, it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *21 CFR § 1306.04(a).* The usual course of professional practice arguably involves such factors as the practitioner's medical specialty, his or her professional training and applicable practice guidelines. Many general practitioners, for example, lack the expertise and professional training necessary to effectively treat severe and chronic pain with Schedule II opioids. Many general practitioners do not understand that not all pain requires opioids and not all pain patients are appropriate candidates to receive opioids. I would note that this test also applies to administration and other dispensings. I would also note that while the prescriber bears responsibility for proper prescribing and dispensing, corresponding responsibility rests with the pharmacist who fills the prescription. *21 CFR § 1306.04(a)*.

And lastly, cornerstone number four is the unfortunate reality that opiate analgesics, the controlled substances most commonly prescribed for the treatment of pain, have a high potential for abuse and are frequently diverted to illicit use.

The DEA's Dual Role

The DEA's mission with respect to illicit controlled substances like heroin and crack, is to eliminate them outright. However, the DEA's role is much more complex when it comes to licit controlled pharmaceuticals. On one hand, the DEA prevents, detects, and eliminates the diversion of controlled pharmaceuticals from legitimate channels to illegal use, while at the same time ensuring their availability for legitimate medical and scientific purposes. To facilitate these goals, Congress through the Controlled Substances Act, established a closed system of controlled substance distribution encompassing manufacturers, distributors, pharmacies, and physicians. Components of this closed system include scheduling of all controlled substances, registration of all controlled substance handlers, record keeping for accountability, security and manufacturing quotas, all under the DEA's oversight.

Despite the closed system, controlled substance diversion occurs in many ways. A physician or pharmacist, for example, may trade drugs for money or sex. A physician or pharmacist may divert drugs for their own personal, non-therapeutic use. "Doctor-shopping" patients may feign illness to acquire drugs, and drugs may be obtained through forged prescriptions. Diverted pharmaceuticals are used for other than

legitimate medical purposes including being sold on the street for many times their retail value.

The DEA's Inquiries

There has been a misperception that the DEA investigates all doctors who prescribe significant quantities of narcotic drugs. Contrary to popular belief, dosage quantities and duration of treatment do not alone trigger DEA investigations because there are numerous legitimate reasons for such prescribing or administration patterns. Quantities and types of drugs involved are frequently components of an investigation but alone cannot trigger anything more than a closer look at the activity in question. Dosage quantities and the number of practitioners issuing prescriptions to a specific patient may result in inquiries about that patient if they appear to be "doctor shopping" or they exhibit drug-seeking behavior.

Many drug abusers and dealers visit numerous practitioners to maximize the number of drugs they can obtain. They then spread their prescriptions over a wide geographic area to avoid detection. When inquiring about these individuals, it is often necessary for the DEA and other law enforcement authorities to contact the practitioners who issued the prescriptions, or those whose signatures were forged. These fact-finding inquiries should not imply that the DEA is investigating the practitioner or that he or she is culpable in any way.

DEA Investigations

The DEA investigates practitioners and pharmacists when there is suspicion of criminal activity specifically the "diversion" or sale of controlled drugs or prescriptions without legitimate need. To proceed with criminal or administrative actions, the DEA must have conclusive evidence of wrongdoing such as providing multiple prescriptions to individual patients in fictitious names to avoid detection; trading drugs for sexual favors or money; or providing controlled substance prescriptions to known abusers despite awareness of actual harm or of their arrests for selling the drugs that he had earlier provided.

The DEA works closely with its state counterparts in many investigations. State medical and pharmacy board investigators sometimes provide the DEA with leads on possible criminal activity; the DEA, in turn, often refers possible "unprofessional practice" or misconduct issues to the Boards. Sometimes we conduct investigations together.

The DEA does not define or regulate standards of medical practice. Once it has been decided that criminal prosecution through a state or federal prosecutor's office or administrative action will be pursued, it becomes necessary to engage medical experts in the review process to determine whether specific conduct clearly falls outside the scope of legitimate medical practice.

Federation of State Medical Boards'

"Model Guidelines for the Use of Controlled Substances in the Treatment of Pain"

A much asked question is: "How does a physician know whether his prescribing or administering opiates for pain is appropriate?" The DEA testified in support of the Federation of State Medical Boards' "Model Guidelines for the Use of Controlled Substances in the Treatment of Pain" in March 1998. The DEA endorsed the guidelines because they are consistent with the four cornerstones of the DEA's pain management position referred to earlier. The guidelines are important because they set forth the general principles that doctors should consider in determining legitimate medical need

and legitimate medical practice based on clinical grounds. The guidelines are incompatible with the type of practice that leads to willful, criminal diversion of controlled substances by a practitioner unless the practitioner intentionally falsifies medical diagnoses and records.

When applied conscientiously, the guidelines also minimize the risk of diversion through negligence that often occurs when "doctor shoppers" posing as patients feign illness to obtain drugs for street sale or for personal use. For example, the guidelines require a physician when evaluating a pain patient to take a complete medical history and conduct a physical examination. They require the physician to set down a written treatment plan with objectives, and to conduct reasonable follow-ups to continue or modify therapy. The guidelines also require the physician to comply with applicable controlled substance laws and regulations and to document everything accurately and completely.

When a physician determines that a patient is at risk for medication abuse or has a history of substance abuse, the guidelines suggest a written agreement between the physician and patient outlining patient responsibilities. The guidelines embody a reasonable approach to help maintain the delicate balance between preventing controlled substance diversion and ensuring access by legitimate patients. The guidelines also promote a healthy bona fide physician-patient relationship for the benefit of everyone, especially the patient. I understand that you have copies of these guidelines and that you provide them to practitioners who feel uncomfortable about prescribing opiates for their consideration.

Quantity Limits

Provided there is legitimate medical need, a practitioner may issue a prescription to any patient for any quantity of any controlled substance that he or she deems medically appropriate. There are no limits on the quantity of controlled substance dosage units under federal law or regulation that a practitioner may prescribe. Prescriptions for all drugs except for those in Schedule II may be refilled up to five times during a six-month period but there are no restrictions on the quantities that may be dispensed. *21 CFR 1306.22(a)*. Prescriptions for Schedule II drugs may not be refilled and a new prescription signed by the prescriber must be provided to the pharmacy for each new supply dispensed. *21 CFR 1306.13(a)*. However, some states, and even some insurance providers, do limit controlled substance quantities that practitioners may prescribe.

The DEA's Initiatives

While attempting to stem controlled substance diversion, the DEA has simultaneously undertaken a number of initiatives over the past decade designed to facilitate patient access to needed pain medication. Through extensive participation in seminars, meetings, and conferences, the DEA is trying to dispel the misperception that its regulations and policies impede effective pain management. The DEA includes medical specialists in the fields of pain management and addiction treatment as speakers at conferences attended by law enforcement and regulatory officers. As previously mentioned, the DEA provided testimony in support of the Federation of State Medical Boards' "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." The DEA amended the regulations to allow faxing schedule II narcotic prescriptions for home infusion patients, and those in hospices and Long Term Care Facilities (LTCF). *21 CFR 1306.11(f)*. The DEA also amended the regulations to allow for the partial filling of Schedule II prescriptions for terminally ill or LTCF patients to accommodate changes in medication needs. *21 CFR 1306.13(b)*. In addition, The DEA

is currently engaged in a pilot project that may serve as a basis for new regulations that will allow for secure transmission through faxing or e-mailing of prescriptions for substances in all schedules, again to facilitate patient access.

Perhaps the most important of the DEA's activities has involved aggregate production quotas for analgesics. The DEA has worked with industry and healthcare professionals to increase aggregate production quotas and quotas for strong analgesics have increased significantly over 1990 totals. For example, the 1999 aggregate production quota for fentanyl was 10.4 times what it was in 1990. Nineteen ninety-nine's aggregate production quota for oxycodone was 6.4 times what it was in 1990. The aggregate production quotas for hydrocodone (4.5 times), hydromorphone (3.8 times), and morphine (2.6 times) also increased significantly over the past decade. Additionally, the sheer number of products containing Schedule II substances have increased from three hundred in 1990 to over four hundred in 1997, and over 75 percent of these products are analgesics used to treat pain.

Registrant Responsibilities

Generally, all DEA registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. *21 CFR § 1301.71(a)*. Secondly, a registrant must make a good faith inquiry with the DEA or the appropriate state agency that a recipient of controlled substances, like a doctor or pharmacy is authorized to possess the controlled substance. *21 CFR 1301.74(a)*. Lastly, a registrant must design and operate a system to disclose suspicious controlled substance orders, and to report these suspicious orders to the DEA. *21 CFR § 1301.74(b)*. Suspicious orders include orders of unusual size, orders that deviate substantially from a normal pattern, and orders of unusual frequency.

Forged Prescriptions

One of the most common ways to divert controlled pharmaceuticals is through prescription forgeries. Currently, the most commonly forged prescriptions are for:hydrocodone products like Vicodin®, Lortabs®, Lorcet®, and Anexsia®; oxycodone products like OxyContin®, Percodan®, Percocet®, and Tylox®; Methylphenidate, or Ritalin®; and benzodiazepines such as alprazolam, diazepam (or Valium®), and lorazepam.

Characteristics of forged prescriptions may include the following factors: the prescription looks "too good or neat;" quantities, directions, or dosages differ from usual medical usage; the prescription appears to be photocopied; directions on the prescription are written in full with no abbreviations; and lastly, the prescription is written in different color inks or written in different handwriting.

The responsibility for proper prescribing and dispensing of controlled substances rests upon the prescribing physician, but a corresponding responsibility rests with the pharmacist who fills the prescription. *21 CFR § 1306.04(a)*. In order to help prevent prescription forgeries, the pharmacist should know the prescriber and his signature. The pharmacist should know or should verify the prescriber's DEA registration number. The pharmacist should know the patient, and the pharmacist should check the date on the prescription order. Perhaps the most effective thing a pharmacist can do, is to verify the prescription and its particulars with the prescribing physician. This can be accomplished with a simple telephone call.

If a pharmacist believes that he has been given a forged, altered, or counterfeit prescription, he should not dispense the medication and he should call the local police.

If a pharmacist believes that he has uncovered a pattern of prescription abuses, he should contact his state board of pharmacy and the local DEA office.

Conclusion

In conclusion, the one thing I would have you remember with respect to the DEA, controlled substances, and pain management is this: a practitioner may prescribe, administer, or dispense any quantity of any controlled substance so long as there is a legitimate medical purpose and he or she is acting in the usual course of professional practice. Practitioner concern about the DEA's oversight is unwarranted if the practitioner is handling the controlled pharmaceuticals appropriately based upon legitimate medical need.

If you encounter practitioners concerned about regulatory scrutiny, provide them with a copy of the Federation of State Medical Boards' Guidelines, refer them to the DEA Diversion website:

(www.DEAdiversion.usdoj.gov),

or refer them to the local DEA office. If you encounter potential diversion of controlled substances, report it to your supervisor, and/or contact the DEA. I encourage you to use the DEA as a resource. We have a number of publications on these and other related topics which are available through the DEA Diversion website or by contacting the Liaison and Policy Section at the DEA headquarters. Staffers at the DEA headquarters and diversion investigators in the field are there to advise and assist you.

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